

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

AMERICAN FEDERATION OF STATE, COUNTY
AND MUNICIPAL EMPLOYEES, DISTRICT
COUNTY 47 HEALTH AND WELFARE FUND, *et al.*
Plaintiffs,

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v.

PURDUE PHARMA L.P. and THE PURDUE
FREDERICK COMPANY INC.

Defendants.

Civil Action No. 1:07-cv-08761-JGK

**THE PURDUE DEFENDANTS' REPLY BRIEF
IN SUPPORT OF THEIR MOTION FOR JUDGMENT ON THE PLEADINGS**

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INTRODUCTION

As is clear from their brief, Plaintiffs must rely on a wildly speculative theory to link their putative injuries to Purdue's alleged misconduct. Plaintiffs do not contend that OxyContin is unsafe or ineffective when prescribed for the treatment of chronic moderate to severe pain and have no objection to paying for such prescriptions. Indeed, Plaintiffs readily admit that they continue to cover OxyContin (apparently without restrictions) even today. Nor do Plaintiffs argue that they reimbursed their members for a well-defined "off-label" use (*e.g.*, to treat seizures); that they paid an inflated price; or that they would have paid for cheaper alternatives "but for" Purdue's alleged misconduct. Instead, Plaintiffs contend they were harmed because some unknown percentage of the prescriptions they covered were "excessive, unnecessary, abusive, or diverted" *as a result of* Purdue's alleged misconduct. (*See* Compl. ¶ 35.)

This theory creates several insurmountable problems for Plaintiffs. To begin with, Plaintiffs would have to separate medically appropriate prescriptions from those that were not. Next, Plaintiffs must somehow distinguish between prescriptions that were both causally related to Purdue's alleged misconduct *and* "excessive, unnecessary, abusive, or diverted" (to the extent they exist) from those that were "excessive, unnecessary, abusive, or diverted" for reasons unrelated to Purdue. Indeed, Plaintiffs covered at least four categories of "excessive and unnecessary" prescriptions with no connection to Purdue's alleged misconduct: (1) prescriptions caused by the malpractice of the physician; (2) "abusive" prescriptions caused by Plaintiffs' members' desire to get high; (3) "excessive" prescriptions caused by the Plaintiffs' members' "addiction" to or "dependency" on OxyContin; and (4) "diverted" prescriptions (*e.g.*, forged prescriptions) caused by the criminal misconduct of Plaintiffs' members. But that is not all. Plaintiffs must also account for the possibility that the chain of causation could be broken even for those prescriptions that could be somehow linked to Purdue's alleged misconduct. Some of

those prescriptions could still, of course, have been medically appropriate and therefore would not have harmed Plaintiffs. In other cases, the chain of causation could be broken by the illegal conduct of the member or the prescribing physician.

Remarkably, Plaintiffs claim they were powerless to deny coverage of even patently improper prescriptions. Setting aside the fact that this cannot possibly be accurate (there are formulary controls Plaintiffs could have used to address this problem, *e.g.*, prior authorization requirements), this merely accentuates the fact that proof of causation here will depend solely on the “independent choices” of individuals (*i.e.*, doctors and their patients) not before the Court. *See In re Guidant Corp.*, 484 F. Supp. 2d 973, 984 (D. Minn. 2007).

Notwithstanding the fact that they bear the burden to do so, Plaintiffs offer no explanation of how they will surmount the challenges posed by *their own claim*.¹ Nor could they, as the gap between Purdue’s alleged misconduct and Plaintiffs’ purported injuries is far too wide to satisfy the standing requirements of Article III. For these reasons and those set forth below and in Purdue’s opening brief, Plaintiffs’ claims should be dismissed with prejudice.

ARGUMENT

I. Plaintiffs Have Failed To Establish Article III Standing

As the parties invoking federal jurisdiction, Plaintiffs bear the burden of establishing that they have standing under Article III. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332 (2006). Neither the allegations in the Complaint nor Plaintiffs’ Answer to Purdue’s Motion for Judgment on the Pleadings establish that the requirements of Article III standing are satisfied. Indeed, as noted above, Plaintiffs make no attempt to defend their own theory of injury. Instead, Plaintiffs

¹ Plaintiffs’ sole response to these issues is to incorporate by reference the arguments made by another third-party payor plaintiff, the New Mexico fund, which is proceeding under a completely different theory of injury.

rely solely on the brief filed in *New Mexico Fund v. Purdue, et al.*, No. 07-6916, which offers them no help because it is primarily focused on a completely different theory of injury.²

Here, Plaintiffs assert they were injured by “unnecessary and excessive usage of OxyContin” that was allegedly caused by Purdue’s conduct with respect to “the effects of addiction and dependency” of the drug. (Compl. ¶¶ 15, 48.) In contrast, the *New Mexico* plaintiff asserts that it was injured by paying “for the artificially high costs of filling OxyContin prescriptions” that was allegedly caused by the Defendants use of their “dominant position in the market to charge more for OxyContin” than they otherwise could have. (See *New Mexico* Compl. ¶¶ 72, 75.) Accordingly, the injury in this action is based on allegations regarding the overall quantity of OxyContin prescriptions reimbursed, while the injury in the *New Mexico* action is based on allegations regarding the price paid per OxyContin prescription.

As explained above, Plaintiffs’ theory (although it shares many problems with the *New Mexico* plaintiff’s theory) presents its own unique challenges. For example, the nature of the relief sought by Plaintiffs - recovery for “excessive, unnecessary, abusive, or diverted purchases of OxyContin” - requires Plaintiffs to distinguish between legitimate and illegitimate prescriptions and between illegitimate prescriptions caused by Purdue’s alleged misconduct and those caused by something else. In other words, Plaintiffs’ claims necessarily turn on the independent choices of parties not before this Court, namely physicians who prescribe OxyContin and patients who have either ingested, diverted, or abused it. Indeed, Plaintiffs admit as much in their brief. (See, e.g., Plfs.’ Ans. at 18 (stating that in paying for their members’ prescriptions, “the [Plaintiffs’] actions are driven by the decisions of their members’

² As shown in the reply brief Purdue filed in the *New Mexico* case (which is expressly incorporated herein), the *New Mexico* plaintiff was unable to rescue its own claim, much less those of the Plaintiffs here.

physicians”).) Moreover, the “econometric solution” the *New Mexico* plaintiff offers as a purported cure for the many causation problems presented by its theory of recovery (whether properly deemed a “fraud on the market theory” or not) has no application here where the issue is the number of prescriptions filled, not the price. Consequently, the portion of the *New Mexico* Answer that addresses Article III standing - which primarily relies on other “overpricing” cases - does not address Purdue’s argument as to why the requirements of Article III standing are not met in this action. Having failed even to defend their own standing to sue, Plaintiffs’ claims should be dismissed.

II. Plaintiffs Fail To State A Claim Under The UTPCPL

A. Plaintiffs Do Not Purport to Represent Their Members.

Plaintiffs rely on *Commonwealth v. TAP Pharmaceutical Products, Inc.*, 885 A.2d 1127 (Pa. Commw. 2005), for the proposition that a third-party payor has standing to assert UTPCPL claims for its routine reimbursement of prescription drugs. In *TAP*, the Commonwealth of Pennsylvania, in its status of *parens patriae*, asserted UTPCPL claims on behalf of Pennsylvania citizens who alleged injuries in the form of inflated payments for prescription drugs. *Id.* Unlike Plaintiffs here, the Commonwealth sought “to pursue the alleged damages of individual consumers in Pennsylvania.” *Id.* at 1143. The argument of the Commonwealth, which the *TAP* court found persuasive, was that its UTPCPL standing arose “not from its position as a business enterprise, but rather in its capacity as a representative of its constituents.” *Id.* at 1142. Similarly, in *Valley Forge*, also relied on by Plaintiffs, a condominium association was found to have UTPCPL standing because it was statutorily authorized to “act in a representative capacity on behalf of the unit owners when contracting, and when bringing suit.” *Valley Forge Towers South Condominium v. Ron-Ike Foam Insulators, Inc.*, 574 A.2d 641, 649 (Pa. Super. 1990).

In contrast to *TAP* and *Valley Forge*, Plaintiffs are not suing in a representative capacity to recover for injuries to their insureds. Nor have they cited any statutory authority that would permit them to do so even if they had. Instead, Plaintiffs assert that *they* suffered a direct injury to their business interests. (*See* Compl. ¶ 15 (“The Funds were injured as a result of the unlawful conduct alleged herein”); Plfs.’ Answer at 14-15 (“it is difficult to imagine who was more directly injured. . . than the very party that made the payments”); *id.* at 16 (“There was nothing incidental or remote about the damage to the Plaintiff funds”).³ Reduced to its essence, Plaintiffs argument is that the UTPCPL permits it to recover damages for itself based on someone else’s alleged use of a product for personal, family, or household purposes. Plaintiffs have cited no case law to support such an expansive (and practically limitless) interpretation of the UTPCPL, and Purdue is unaware of any such authority. *See, e.g., Balderston v. Medtronic Sofamor Danek, Inc.*, 285 F.3d 238, 242 (3d Cir. 2002) (in a UTPCPL action, the court “uncovered no Pennsylvania decision finding actionable a non-representative plaintiff’s claim based on others’ ‘personal uses’”). Accordingly, Plaintiffs lack standing under the UTPCPL.

B. The Learned Intermediary Doctrine and the UTPCPL are Incompatible

Plaintiffs cite *Heindel v. Pfizer*, 381 F.Supp.2d 364 (D.N.J. 2004), for the broad proposition that “[t]he learned intermediary doctrine does not apply in this case.” (Plfs.’ Ans. at 8.) The *Heindel* court, however, held that UTPCPL claims are barred by the learned intermediary doctrine. *Heindel*, 381 F.Supp.2d at 384 (“Defendants claim that Plaintiffs’ UTPCPL claim is barred by the learned intermediary doctrine. For several reasons, the Court

³ In their class definition, Plaintiffs purport to sue “on behalf of themselves and their beneficiaries or insureds.” (Compl. ¶ 35.) It is not at all clear from either the Complaint or their brief what they mean by this. Indeed, throughout the Complaint and brief, Plaintiffs refer only to damages they themselves claim to have suffered. There is no mention at all of harm to their “beneficiaries or insureds.” Moreover, Plaintiffs never cite or plead any legal authority that would permit them to act “on behalf” of their “beneficiaries or insureds.”

finds that Plaintiffs' claims are indeed barred by the learned intermediary doctrine”).

Accordingly, *Heindel* refutes, rather than supports Plaintiffs’ position.

Plaintiffs also argue that their UTPCPL claim is not barred by the learned intermediary doctrine because it is based on Purdue’s promotional and advertising practices. (*See* Plfs.’ Ans. at 8.) As set forth in Purdue’s initial brief, Pennsylvania courts have explicitly refused to create an exception to the learned intermediary doctrine based on a prescription drug manufacturer’s promotional or advertising efforts. *See Albertson v. Wyeth, Inc.*, 63 Pa. D. & C. 4th 514, 539 (Pa. Com. Pl. 2003) (reasoning that “[m]edia dissemination of information concerning the existence of these drugs does not enhance the public’s ability to acquire them. . . the consumer still required a prescription from a physician, a learned intermediary”).

Plaintiffs assert that the reasoning of *Albertson* is inapplicable because Plaintiffs allege Purdue promoted OxyContin for “non-medically necessary, non-indicated uses.” (Plfs.’ Ans. at 8, citing Compl. ¶¶ 18-19.) In fact, similar allegations were also at issue in *Albertson*:

Premarin and Prempro were designed and have been approved by the FDA to relieve only menopausal symptoms. . . However, according to plaintiffs, Wyeth has long touted its estrogen products as having additional benefits. . . Wyeth claimed that Alzheimer’s disease, vision problems, tooth loss, heart disease and colon cancer could be treated with Premarin or Prempro. Wyeth also suggested that its conjugated equine estrogen was appropriate for treating or preventing, among other things, memory loss, colon cancer and age-related vision loss.

Albertson, 63 Pa. D. & C. 4th at 517-18. The fact that Wyeth allegedly promoted its drugs for non-indicated uses did not change the result: the *Albertson* plaintiffs’ UTPCPL claims were barred by the learned intermediary doctrine just as they are in this case.

As shown in Purdue’s opening brief and its reply to the *New Mexico* plaintiff’s brief, *See New Mexico Reply Brief* at Sect. VI, application of generalized *consumer* protection regulations like the UTPCPL to prescription medications would subvert the regulatory paradigm applicable to prescription drugs because it would compel drug makers to provide drug safety information

directly to *consumers* instead of the *doctors* who are in the best position to understand and apply it to their patients. *See, e.g., Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (rejecting a claim under the New York consumer protection law on the basis of the learned intermediary doctrine). For the same reason, application of such statutes to prescription drugs would also undermine federal regulation of prescription drugs, which, like the learned intermediary doctrine, is focused on the flow of information between pharmaceutical companies and physicians. *See* 71 Fed. Reg. 3922, 3961 (item 112), 3968 (Jan. 24, 2006) (“Requiring that language used in prescription drug labeling be tailored to a lay audience would result in a loss of clarity and precision needed to effectively communicate to practitioners.”).

C. This Court Should Require Plaintiffs to Allege the Elements of Common Law Fraud to State a Claim Under the UTPCPL Catch-All Provision

Although Plaintiffs are correct that the “catch-all” provision of the UTPCPL, 73 P.S. § 201-2(4)(xxi), was amended in 1996 to prohibit both fraudulent and deceptive conduct, they are not correct that this amendment obviated the need to plead reliance and the other elements of common law fraud. In fact, numerous decisions issued after the 1996 amendment have required the elements of common law fraud to be pled in order to state a claim under the catch-all provision.⁴ To the extent there is a dispute in the case law on this issue, this court, as a federal court applying Pennsylvania law, should apply the view that limits liability until the Supreme

⁴*See, e.g., Morilus v. Countrywide Home Loans, Inc.*, Civ. No. 07-0900, 2007 U.S. Dist. LEXIS 44943, *17 (E.D. Pa. June 20, 2007); *Yurchak v. Atkinson & Mullen Travel, Inc.*, 207 Fed. Appx. 181, 184 (3d Cir. 2006); *Arnold v. Stein Roe & Farnham*, Civ. No. 06-243, 2006 U.S. Dist. LEXIS 14924, *4 (D. Pa. Mar. 31, 2006); *Ephraim v. eHomeCredit Corp.*, No. 3:04-cv-2337, 2006 U.S. Dist. LEXIS 13916, *9 (D. Pa. Mar. 13, 2006); *Colaizzi v. Beck*, 895 A.2d 36, 39 (Pa. Super. Ct. 2006); *Rock v. Voshell*, 397 F. Supp. 2d 616, 622 (E.D. Pa. 2005); *Fresh Start Indus. v. ATX Telecomms. Servs.*, 295 F. Supp. 2d 521, 528 n. 7 (D. Pa. 2003); *Skurnowicz v. Lucci*, 798 A.2d 788 (Pa. Super. 2002); *Grant v. Kingswood Apts.*, Civ. No. 01-1523, 2001 U.S. Dist. LEXIS 23927, *8 (D. Pa. Oct. 15, 2001); *Booze v. Allstate Ins. Co.*, 750 A.2d 877 (Pa. Super. 2000); *Fay v. Erie Ins. Group*, 723 A.2d 712 (Pa. Super. 1999); *Sewak v. Lockhart*, 699 A.2d 755 (Pa. Super. 1997); *DiLucido v. Terminix Int'l, Inc.*, 676 A.2d 1237 (Pa. Super. 1996).

Court of Pennsylvania expressly addresses the divergent views. This is particularly true given that the Pennsylvania Supreme Court has, in the past, consistently required UTPCPL plaintiffs to plead the elements of common law fraud and, as one federal court has predicted, is likely to do so again here. *Grant v. Kingswood Apts.*, Civ. No. 01-1523, 2001 U.S. Dist. LEXIS 23927, *8 (D. Pa. Oct. 15, 2001) (emphasis added) (predicting that the Pennsylvania supreme court would conclude that “*all claims* of . . . ‘unfair or deceptive acts or practices’ under the UTPCPL must be pled with the same specificity as a common-law fraud claim.”)

Not surprisingly, federal courts have routinely followed this approach.⁵ As one of those courts recently put it:

Disagreement exists among some lower Pennsylvania state courts and Pennsylvania federal district courts as to whether reliance is necessary under the UTPCPL’s “catch-all” provision. . . [h]owever, since a federal court must follow state law as announced by the highest state court when the highest state court has spoken on the issue, this Court will follow the Pennsylvania Supreme Court’s assessment of the pleading requirements under the UTPCPL, *which includes reliance*.

Atlass v. Mercedes-Benz USA, LLC, Civ. No. 07-2720, 2007 U.S. Dist. LEXIS 72603, *12 (D.N.J. Sept. 25, 2007) (internal citations omitted) (emphasis added).

Further, this Court should not, as Plaintiffs suggest, find that Plaintiffs are entitled to a presumption of reliance under the UTPCPL. When evaluating whether to presume reliance, “courts have looked to the nature of the parties’ relationship and materiality of the statement . . .

⁵ See, e.g., *Ephraim v. eHomeCredit Corp.*, No. 3:04-cv-2337, 2006 U.S. Dist. LEXIS 13916, *9 (D. Pa. Mar. 13, 2006) (“The Amended Complaint does not allege that the defendants engaged in fraudulent conduct. However, to assert a cause of action under [the UTPCPL catch-all] the plaintiff must indeed prove all the elements of common-law fraud. . . Plaintiff’s position is that such allegations do not have to be made. His position is not supported by the Pennsylvania Superior Court’s most recent holding on this subject”); *Fresh Start Indus. v. ATX Telecomms. Servs.*, 295 F. Supp. 2d 521, 528 n. 7 (D. Pa. 2003) (observing the divergent views and assuming, without deciding, that reliance must be pled under the UTPCPL catch-all); *Rock v. Voshell*, 397 F. Supp. 2d 616, 622 (E.D. Pa. 2005) (dismissing UTPCPL claims and reasoning that “[w]hile there is some uncertainty as to the requirements in proving a UTPCPL case under the catch-all provision, Pennsylvania courts have recently held that all of the fraud elements are still required, even with the addition of the ‘deceptive’ language”).

.” *Zwiercan v. GMC*, 58 Pa. D. & C.4th 251, 263 (Pa. C.P. 2002). Neither factor warrants a presumption of reliance in this case and none of the cases Plaintiffs cite suggest otherwise. Indeed, the cases Plaintiffs cite refer to circumstances in which reliance on an omission can be presumed because a duty to speak exists. *See, e.g., Katlin v. Tremoglie*, 43 D. & C.4th 373, 391 (Pa. C.P. 1999) (reliance presumed where a physician who was not licensed did not communicate that fact to his patients; the defendant physician had a duty to speak based on the nature of the doctor-patient relationship); *see also Drayton v. Pilgrim’s Pride Corp.*, Civ. No. 03-2334, 2004 WL 765123, *7 (E.D. Pa. Mar. 31, 2004) (reliance presumed in an action involving failure to disclose that poultry was contaminated because the consumers “must rely upon what the manufacturer discloses in order to make a purchasing decision”); *accord Zwiercan*, 58 Pa. D. & C.4th at 263 (applying similar reasoning to find a car manufacturer has a duty to communicate a latent defect to consumers).

Purdue had no such duty to or special relationship with Plaintiffs here. Moreover, the focus of Plaintiffs’ claims is not on any alleged “omissions” concerning the safety and efficacy of OxyContin, but on alleged affirmative misrepresentations. (Compl. ¶ 34 (“In particular, Defendants’ employees were instructed to and did make misleading and false promotional statements about OxyContin to healthcare professionals”)) It makes no sense to impose a presumption of reliance where, as here, the UTPCPL claim at issue is premised on alleged misstatements. *See, e.g., Aronson v. Greenmountain.com*, 809 A.2d 399, 405 (Pa. Super. Ct. 2002) (finding that a proposed class is not entitled to a presumption of reliance in a UTPCPL action based on affirmative misstatements in advertising; such a presumption would be contrary to Pennsylvania Supreme Court precedent because it would allow a plaintiff to pursue an action

for allegedly false advertisements without proof that the plaintiff actually viewed the advertisements).

Additionally, neither the authority cited in Plaintiffs' Answer nor the allegations in the Complaint support a finding that Purdue's alleged misconduct was in any way material to Plaintiffs' decision to cover OxyContin. *See, e.g., Peerless Wall & Window Covering v. Synchronics, Inc.*, 85 F. Supp. 2d 519, 534 (D. Pa. 2000) (fraud claim dismissed because "here, there is no evidence that plaintiff would not have acquired defendant's software in 1994 had it been disclosed that it was not Y2K-compliant") (cited in Plfs.' Ans. at 13). As in *Peerless*, there is no evidence that Plaintiffs would not have covered OxyContin absent Purdue's alleged misconduct. To the contrary, Plaintiffs own conduct directly indicates otherwise -- even knowing the information they claim would have changed their coverage decision, Plaintiffs continued to cover OxyContin even after filing this lawsuit. (*See* Plfs.' Ans. at 18-19.)

III. Plaintiffs' Allegations Do Not Support Its Claim For Unjust Enrichment

Plaintiffs assert they have stated a claim for unjust enrichment because (1) third-party payors have been permitted to maintain unjust enrichment claims in other circumstances, and (2) Plaintiffs are obligated to pay for their members' OxyContin prescriptions. Neither argument overcomes the deficiencies of the Complaint.

First, Plaintiffs' reliance on overpricing and antitrust cases is misplaced. (*See* Plfs.' Ans. at 14-17.) Unlike this action, the plaintiffs in those cases focused on misconduct that directly affected the price of the prescription drug at issue. *See, e.g., Commonwealth v. TAP Pharmaceutical Products, Inc.*, 885 A.2d 1127 (Pa. Commw. 2005) (defendant inflated the Average Wholesale Price of prescription drugs); *In re Lorazepam & Clorazepate Antitrust Litigation*, 295 F. Supp. 2d 30 (D.D.C. 2003) (defendant entered into agreements to restrain trade and control the price of prescription drugs); *In re Cardizem CD Antitrust Litigation*, 105 F.

Supp. 2d 618 (D. Mich. 2000) (defendant artificially inflated the price of prescription drugs by stopping generic drugs from entering the market).

Plaintiffs' reliance on *In re Pa. Baycol Third-Party Payor Litigation*, Civ. No. 1874, 2005 Phila. Ct. Com. Pl. LEXIS 129 (C. P. Phila. Apr. 4, 2005), in which a Pennsylvania trial court held that third-party payors stated a claim for unjust enrichment against a prescription drug manufacturer, is similarly misplaced. Notably, in *Baycol*, the defendant had ceased distribution of the drug and advised all known users to immediately cease using it. *Id.* at *1. In evaluating the first two elements of an unjust enrichment claim, the court found this fact to be dispositive:

An unjust enrichment class requires answers to the following common questions of fact: (1) did plaintiffs confer a benefit upon defendants, (2) did the defendants appreciate the benefit. These questions must be answered in the affirmative since the ***plaintiffs' present a claim only to the extent that they paid defendants for Baycol which the company thereafter strongly urged consumers not to use.***

Id. at *22 (emphasis added). Accordingly, the "benefit" that was considered sufficient to state a claim in *Baycol* was payment for a drug that plaintiffs alleged should never have been on the market in the first place. The reasoning of *Baycol* is consistent with the argument set forth in Purdue's initial brief -- Plaintiffs' unjust enrichment claim must fail in light of their continued reimbursement of their members' OxyContin prescriptions. (See Def.'s Mot. at 26.)

Plaintiffs argue that the cases relied on by Purdue, which barred unjust enrichment claims brought by plaintiffs who continued to use and pay for the products at issue, can be distinguished because they involved individuals as opposed to third-party payors. The reasoning of those cases is not specific to individual consumers, however, and Plaintiffs present no persuasive argument as to why the reasoning of *Whalen* and *Prohias* is inapplicable to third-party payors. See *Whalen v. Pfizer, Inc.*, 600125/05, 2005 WL 2875291, at *2 (N.Y. Sup. Ct. Sept. 22, 2005); see also *Prohias v. Pfizer, Inc.*, 485 F.Supp.2d 1329, 1334-35 (S.D. Fla. 2007).

Remarkably, Plaintiffs also assert that their hands are tied when it comes to OxyContin: they claim that they must continue covering OxyContin because they “are obligated to pay for their members’ prescriptions and cannot unilaterally deny payment” and “those members are entitled to payment of prescription costs, subject to the terms of their collective bargaining agreements and benefit plans.” (*See* Plfs.’ Ans. at 18-19.) Even more remarkably, Plaintiffs contend that they “continue to be victimized by [wrongful overpromotion of OxyContin].” (*Id.* at 19). In other words, they contend that, even after filing this lawsuit, they are contractually bound to cover “excessive, unnecessary, abusive, [and] diverted” OxyContin prescriptions. Setting aside whether or not this is a credible assertion, this is a problem of Plaintiffs’ own making. Plaintiffs should not be permitted to use contractual obligations they freely entered into *with their members* to reimburse OxyContin prescriptions as the basis for suing *Purdue*.

IV. There is No Implied Warranty Claim Under These Circumstances

Plaintiffs fail to distinguish *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Super. Ct. 1987), which held that a breach of implied warranty claim could not be maintained in connection with the sale of prescription drugs. The holding of *Makripodis* is not, as Plaintiffs argue, dependent on the various relationships between drug manufacturers, physicians, pharmacists, and consumers. (*See* Plfs.’ Ans. at 21.) Rather, the *Makripodis* court refused to recognize an implied warranty of merchantability based on “the very nature of prescription drug themselves.” *Makripodis*, 523 A.2d at 377. As set forth in *Purdue*’s initial brief, this principle has been recognized by courts that have extended *Makripodis* to bar implied warranty claims against prescription drug manufacturers.

Summarily dismissing the two federal cases cited by *Purdue*, Plaintiffs urge this court not to follow *Makripodis* “in the absence of guidance from any Pennsylvania state courts.” (Plfs.’ Ans. at 21.) The problem is that this issue *has* been addressed by Pennsylvania state courts. In

Luke v. American Home Products Corp., No. 1998-C-01977, 1998 WL 1781624 (Pa.Com.Pl. Nov. 18, 1998), for example, a Pennsylvania state court reasoned that:

The discussion in *Makripodis* analyzing the nature of prescription drugs applies in the instant action. Dexfenfluramine hydrochloride, like most prescription drugs, may never be able to be manufactured so that it is safe for every user. Nonetheless, the public utility of the drug may outweigh the potentially dangerous risk dexfenfluramine hydrochloride poses to some individuals. Therefore, the *Makripodis* holding that prescription drugs preclude the imposition of a warranty of fitness for ordinary purposes in cases against pharmacists would reasonably appear to apply in this case against the drug manufacturer. Accordingly, we find that there is no cause of action for a breach of implied warranty in prescription drug cases involving drug manufacturers.

Id. at *6; *see also Lennon v. Wyeth-Ayerst Laboratories, Inc.*, No. 1793 EDA 2000, 2001 WL 755944 (Pa. Super. Ct. June 14, 2001) (application of *Makripodis* by the Superior Court of Pennsylvania to bar an implied warranty claim brought against a drug manufacturer in connection with the sale of a vaccine).

V. The Economic Loss Doctrine Bars Plaintiffs' Negligence Claim

Plaintiffs argue that they may maintain a negligence claim under *Bilt-Rite Contractors, Inc. v. Architectural Studio*, 886 A.2d 270 (Pa. 2005). In *Bilt-Rite*, a contractor asserted a negligent misrepresentation claim, based on Section 552 of the Restatement (Second) of Torts, against an architecture firm in connection with the construction of a new school. The narrow decision announced by the Pennsylvania Supreme Court was to “adopt Section 552 as the law in Pennsylvania in cases where information is negligently supplied by one in the business of supplying information, such as an architect or design professional.” *See id.* at 287-88. The exception announced in *Bilt-Rite* is inapplicable to this action for several reasons.

As an initial matter, Plaintiffs have asserted a claim for negligence, not negligent misrepresentation. (*See* Compl. ¶¶ 65-68.) Even assuming Plaintiffs intended to assert a claim for negligent misrepresentation, however, such a common law negligent misrepresentation claim

would not be within the scope of *Bilt-Rite*. See *Excavation Techs. v. Columbia Gas Co.*, 936 A.2d 111, 114-15 (Pa. Super. Ct. 2007) (concluding that *Bilt-Rite* is limited to Section 552 negligent misrepresentation claims and that “for common law negligent misrepresentation claims the economic loss rule still applies”).

Although some courts have attempted to expand the scope of *Bilt-Rite*, the more reasoned approach is for this court, as a federal court applying Pennsylvania law, to follow those courts that have restricted *Bilt-Rite* to its narrow holding given the absence of any indication that the Pennsylvania Supreme Court intended otherwise. See, e.g., *id.* at 116 (“We view the Supreme Court’s adoption of Section 552 as drawing a narrow exception to the application of the economic loss rule in the particular set of circumstances that were present in *Bilt-Rite*. The Supreme Court made clear in its rationale that application of Section 552 liability for economic loss was limited to design professionals, such as architects”); see also *Hults v. Allstate Septic Sys.*, Civ. No. 4:06-0541, 2007 U.S. Dist. LEXIS 56728, *28 (M.D. Pa. Aug. 3, 2007) (“the holding in *Bilt-Rite* does not appear to have been intended to extend beyond the parameters set forth by the Pennsylvania Supreme Court, namely to negligent misrepresentation cases involving those individuals who are in the business of providing information for use by third parties, such as architects and design professionals”); *Rock v. Voshell*, Civ. No. 05-1468, 2005 U.S. Dist. LEXIS 36942, *4 (E.D. Pa. Dec. 29, 2005) (same).

Finally, contrary to Plaintiffs’ argument, Pennsylvania precedent does, in fact, support application of the economic loss doctrine to this action.⁶

⁶ For example, *Lennon*, discussed *supra*, was a purported class action involving an oral vaccine. No allegations of physical injury were at issue. The plaintiffs only alleged an economic injury, seeking to recover from the defendant drug manufacturer “for themselves and all American recipients of the vaccine, any expenditures for inoculation.” *Id.* at *1. In analyzing the application of the economic loss doctrine to the action, the court observed that “[i]t has also long been settled that ‘no cause of action exists for negligence that causes only economic loss.’” The Complaint contains no allegation that the child suffered

VI. Plaintiffs Have No Claim Under the Restatement (Second) of Torts § 402(B)

As set forth in Purdue's initial brief, to state a claim under this provision, the Complaint must allege (1) there has been physical harm to a consumer, and (2) the physical harm to consumers was caused by justifiable reliance upon the defendant's misrepresentations of material fact. Plaintiffs assert the first element is satisfied because the Complaint alleges the putative class incurred costs "from the effects of addiction and dependency." (Plfs.' Ans. at 24, citing Compl. ¶ 48.) To begin with, section 402(B) simply was not intended to permit a plaintiff to recover economic damages associated with physical harm to *some unnamed and never-to-be identified person not even before the Court*. On the contrary, as the commentary to section 402(B) makes clear, the rule is "limited to strict liability for *physical harm to consumers of the chattel*." Restatement (Second) of Torts § 402(B) Cmt. 3(i)(1965) (emphasis added). By "consumer," the drafters meant "one who makes use of the chattel in the manner which a purchaser may be expected to use it." *Id.* Plaintiffs simply do not qualify as "consumers" under this definition.⁷

CONCLUSION

For the foregoing reasons and those set forth in Purdue's initial brief, Purdue respectfully requests that the Court dismiss Plaintiffs' Complaint with prejudice.

s/ Donald I Strauber
 Donald I. Strauber
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personal injury, only that the Appellants sustained economic harm. Thus, the trial court properly found that Appellants had stated no claim on which relief could be granted as to Appellees' alleged failure to warn, and preliminary objections were justifiably sustained." *Id.* at *2 (internal citations omitted).

⁷ To avoid repetition, Purdue incorporates Sections IV and VI of its Reply Brief filed in Support of its Motion for Judgment on the Pleadings in *New Mexico Fund v. Purdue et al.* Sections IV and VI respond to Plaintiffs' argument that their claims are neither preempted nor time-barred on grounds such as concealment and cross-jurisdictional tolling.

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